APPENDIX A

PENDING CLAIMS

22. A method of treating a human cancer patient having a human malignancy, comprising administering regionally to said patient an amount of an adenovirus composition effective to prevent growth of malignant cells, wherein said adenovirus composition comprises an adenovirus vector construct comprising a p53 gene, dispersed in a pharmacologically acceptable solution.

23. The method of claim 22, wherein said adenoviral composition is administered to the patient by infusion over a period of time.

24. The method of claim 23, wherein said period of time is about 48 hours.

25. The method of claim 22, wherein said amount comprises between about 10^3 to about 5 x 10^{12} adenovirus particles.

26. The method of claim 25, wherein said amount comprises between about 10^3 to about 10^6 adenovirus particles.

27. The method of claim 25, wherein said amount comprises between about 1 x 10^{10} to about 5 x 10^{12} adenovirus particles.

28. The method of claim 25, wherein said amount comprises about 1 x 10^{10} virus particles.

29. The method of claim 25, wherein said amount comprises about 3 x 10^{10} virus particles.

30. The method of claim 25, wherein said amount comprises about 5 x 10^{12} adenovirus particles.

31. The method of claim 22, further comprising at least a second administration of the adenoviral composition.

32. The method of claim 31, further comprising at least a third administration of the adenoviral composition.

33. The method of claim 32, wherein the third administration occurs at least about one day after the second administration.

34. The method of claim 32, wherein the third administration occurs about one day after the second administration.

35. The method of claim 32, wherein said first, second, and third administrations are each given on three consecutive days.

36. The method of claim 22, further comprising resecting a tumor of said cancer patient.

37. The method of claim 22, wherein said resecting occurs prior to said administering.

38. The method of claim 22, wherein said adenoviral composition further comprises phosphate-buffered saline with about 1% (v/v) glycerol.

39. The method of claim 22, wherein said adenoviral composition is delivered in a volume of about 10 ml or less.

40. The method of claim 22, wherein the wild-type p53 gene is under the control of a CMV promoter.

41. The method of claim 22, wherein said growth is prevented by apoptosis.

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42. A method of treating a human cancer patient comprising administering intravenously to said patient an amount of an adenovirus composition effective to prevent growth of malignant cells, wherein said adenovirus composition comprises an adenovirus vector construct comprising a p53 gene, dispersed in a pharmacologically acceptable solution.

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43. The method of claim 42, wherein said adenoviral composition is administered to the patient by intravenous infusion over a period of time.

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44. The method of claim 43, wherein said period of time is about 48 hours.

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45. The method of claim 42, wherein said amount comprises between about 10^3 to about 5 x 10^{12} adenovirus particles.

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46. The method of claim 45, wherein said amount comprises between about 10^3 to about 10^6 adenovirus particles.

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47. The method of claim 45, wherein said amount comprises between about 1 x 10^{10} to about 5 x 10^{12} adenovirus particles.

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48. The method of claim 42, further comprising at least a second administration of the adenoviral composition.

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49. The method of claim 48, further comprising at least a third administration of the adenoviral composition.

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50. The method of claim 49, wherein the third administration occurs at least about one day after the second administration.

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51. The method of claim 49, wherein the third administration occurs about one day after the second administration.

37 52. The method of claim 49, wherein said first, second, and third administrations are each given on three consecutive days.

25 53. The method of claim 42, further comprising resecting a tumor of said cancer patient.

26 54. The method of claim 42, wherein said resecting occurs prior to said administering.

27 55. The method of claim 42, wherein said adenoviral composition further comprises phosphate-buffered saline with about 1% (v/v) glycerol.

28 56. The method of claim 42, wherein said adenoviral composition is delivered in a volume of about 10 ml or less.

29 57. The method of claim 42, wherein the wild-type p53 gene is under the control of a CMV promoter.

30 58. The method of claim 42, wherein said growth is prevented by apoptosis.

38 59. A method of treating a human cancer patient comprising instilling intratracheally to said patient an amount of an adenovirus composition effective to effective to prevent growth of malignant cells, wherein said adenovirus composition comprises an adenovirus vector construct comprising a p53 gene, dispersed in a pharmacologically acceptable solution.

39 60. The method of claim 59, wherein said adenoviral composition is administered to the patient by infusion over a period of time.

49 61. The method of claim 60, wherein said period of time is about 48 hours.

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62. The method of claim 59, wherein said amount comprises between about 10^3 to about 5 x 10^{12} adenovirus particles.

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63. The method of claim 59, wherein said amount comprises between about 10^3 to about 10^6 adenovirus particles.

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64. The method of claim 63, wherein said amount comprises between about 1 x 10^{10} to about 5 x 10^{12} adenovirus particles.

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65. The method of claim 63, wherein said amount comprises about 1 x 10^{10} virus particles.

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66. The method of claim 63, wherein said amount comprises about 3 x 10^{10} virus particles.

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67. The method of claim 63, wherein said amount comprises about 5 x 10^{12} adenovirus particles.

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68. The method of claim 59, further comprising at least a second administration of the adenoviral composition.

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69. The method of claim 68, further comprising at least a third administration of the adenoviral composition.

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70. The method of claim 69, wherein the third administration occurs at least about one day after the second administration.

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71. The method of claim 69, wherein the third administration occurs about one day after the second administration.

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72. The method of claim 69, wherein said first, second, and third administrations are each given on three consecutive days.

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73. The method of claim 59, further comprising resecting a tumor of said cancer patient.

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74. The method of claim 59, wherein said resecting occurs prior to said administering.

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75. The method of claim 59, wherein said adenoviral composition further comprises phosphate-buffered saline with about 1% (v/v) glycerol.

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76. The method of claim 59, wherein said adenoviral composition is delivered in a volume of about 10 ml or less.

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77. The method of claim 59, wherein the wild-type p53 gene is under the control of a CMV promoter.

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78. The method of claim 59, wherein said growth is prevented by apoptosis.

58 79. A method of treating a human cancer patient having a tumor, comprising administering by direct injection of the tumor an amount of an adenovirus composition effective to inhibit growth of tumor cells, wherein said adenovirus composition comprises an adenovirus vector construct comprising a p53 gene, dispersed in a pharmacologically acceptable solution.

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80. The method of claim 79, wherein said amount comprises between about 10^3 to about 5 x 10^{12} adenovirus particles.

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81. The method of claim 80, wherein said amount comprises between about 10^3 to about 10^6 adenovirus particles.

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82. The method of claim 80, wherein said amount comprises between about 1 x 10^{10} to about 5 x 10^{12} adenovirus particles.

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83. The method of claim 82, wherein said amount comprises about 1 x 10^{10} adenovirus particles.

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84. The method of claim 82, wherein said amount comprises about 3 x 10^{10} adenovirus particles.

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85. The method of claim 82, wherein said amount comprises about 5 x 10^{12} adenovirus particles.

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86. The method of claim 79, further comprising at least a second administration of the adenoviral composition.

87. The method of claim 86, further comprising at least a third administration of the adenoviral composition.

88. The method of claim 87, wherein the third administration occurs at least about one day after the second administration.

89. The method of claim 87, wherein the third administration occurs about one day after the second administration.

90. The method of claim 87, wherein said first, second, and third administrations are each given on three consecutive days.

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91. The method of claim 79, further comprising resecting at least part of the tumor of said cancer patient.

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92. The method of claim 79, wherein said resecting occurs prior to said administering.

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93. The method of claim 79, wherein said adenoviral composition is dispersed in phosphate-buffered saline with about 1% (v/v) glycerol.

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94. The method of claim 79, wherein said adenoviral composition is administered in a volume of about 10 ml or less.

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95. The method of claim 79, wherein the wild-type p53 gene is under the control of a CMV promoter.

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96. The method of claim 79, wherein said tumor cells are killed by apoptosis.

97. The method of claim 91, further comprising administering the adenoviral composition to the residual tumor site via direct injection.